Paroxysmal Nocturnal Haemoglobinuria

Participant: 42981 **Trial No: 151604**

Date Issued: 08-February-2016 **Closing Date: 26-February-2016**

Your Results

Sample: 083

Trial Comments

This trial was issued to 155 participants

Sample Comment
This sample was manufactured from stabilised whole blood

Target Cells	Your Result	Median Result	Lower Quartile	Upper Quartile	Number of Returns
RBC PNH Clone - CD59		0.00	0.00	0.00	123
RBC Type II Cells - CD59		0.00	0.00	0.00	110
RBC Type III Cells - CD59		0.00	0.00	0.00	111
Granulocytes PNH Clone - CD24	0.00	0.00	0.00	0.00	94

Performance Monitoring

Sample 083

	Consensus	Your Result	Classification	Running Classification
RBC	Clone Absent	Not Routinely Tested		Red [3]
WBC	Clone Absent	Clone Absent	Within Consensus	Green [1]

1 = All Samples Within Consensus across last 3 samples
2 = 1 Sample Outwith Consensus across last 3 samples
3 = 2 or more Samples Outwith Consensus across last 3 samples
= Not enough samples to determine Running Consensus

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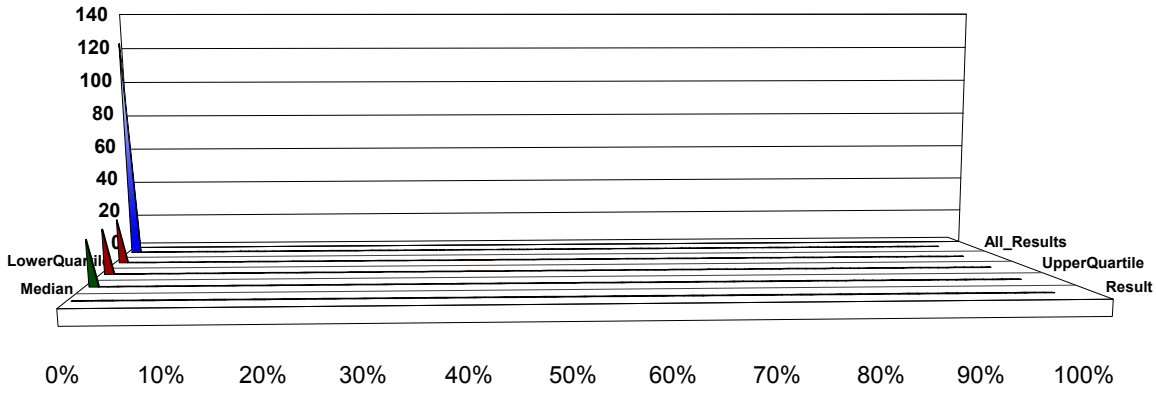
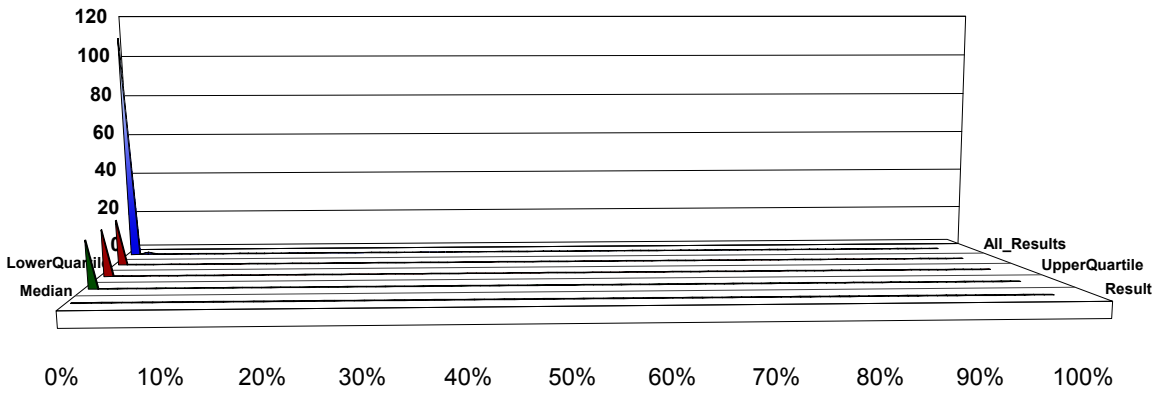
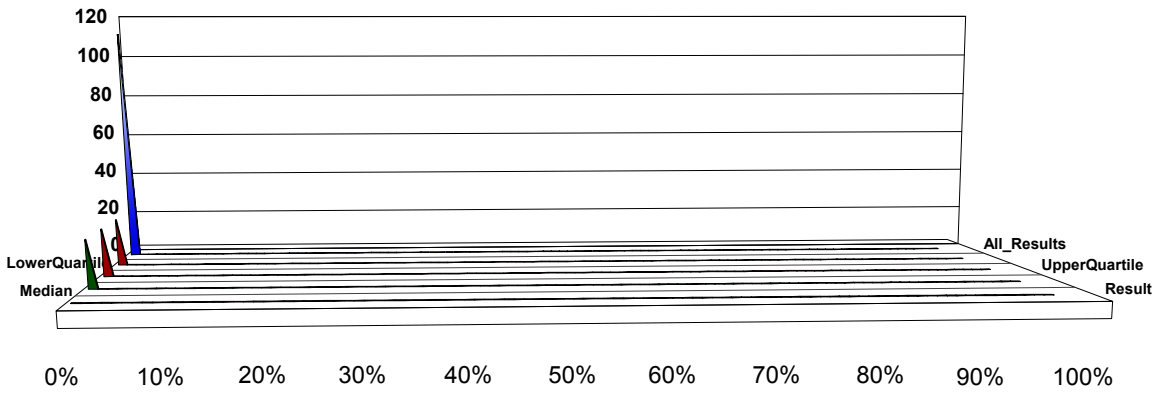
RBC PNH Clone - CD59



RBC Type II Cells - CD59



RBC Type III Cells - CD59



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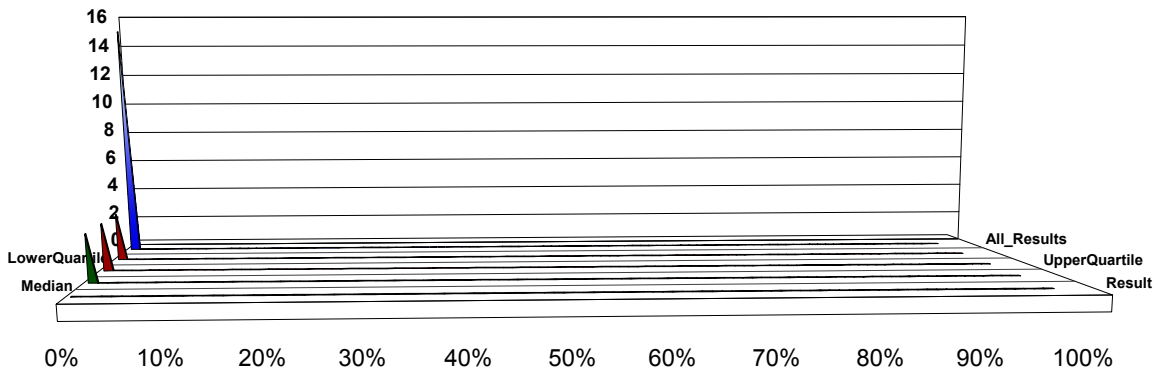
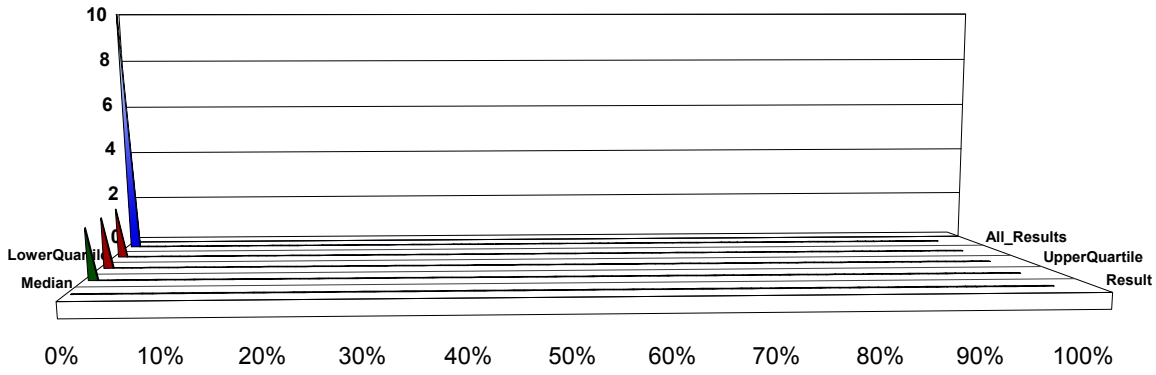
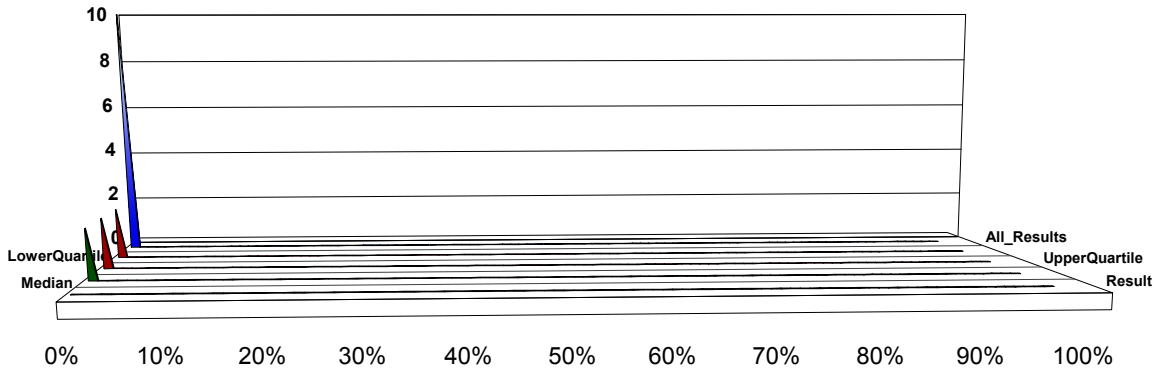
RBC PNH Clone - CD55



RBC Type II cells - CD55



RBC Type III cells - CD55



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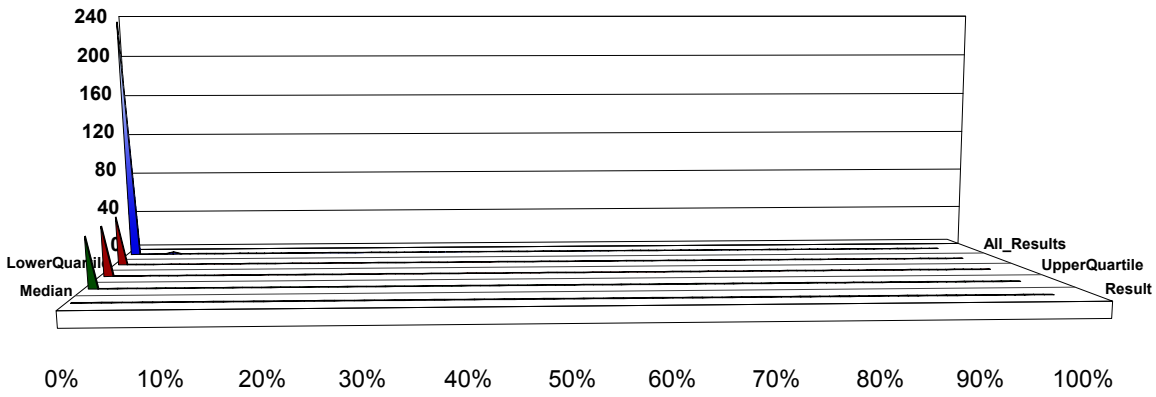
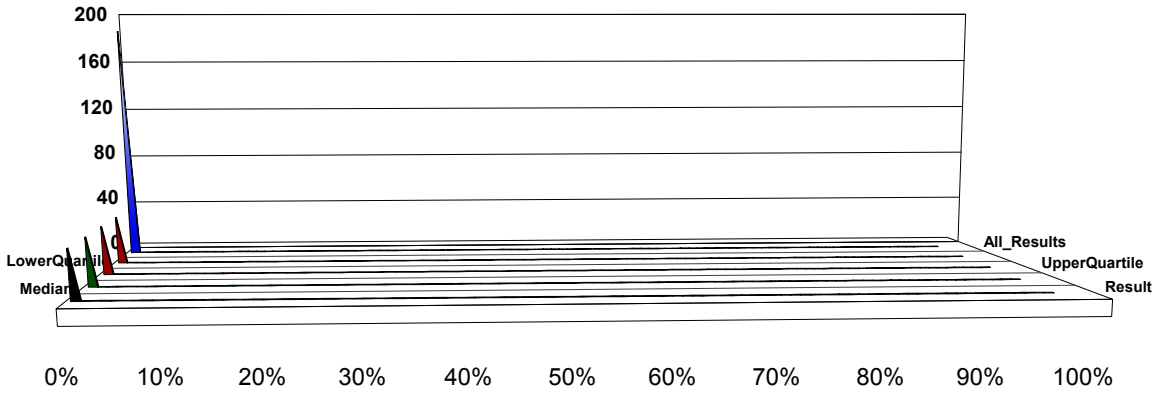
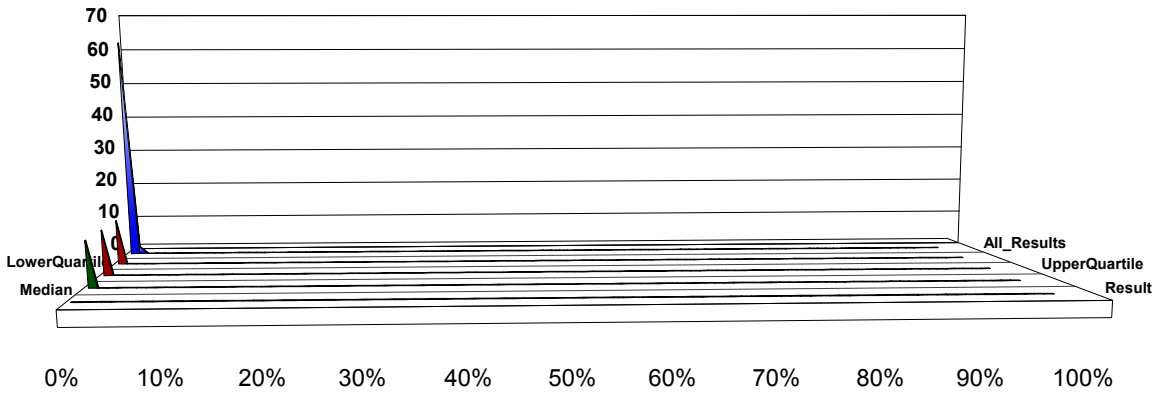
Granulocytes PNH Clone - FLAER



Granulocytes PNH Clone - CD24



Granulocytes PNH Clone - CD16



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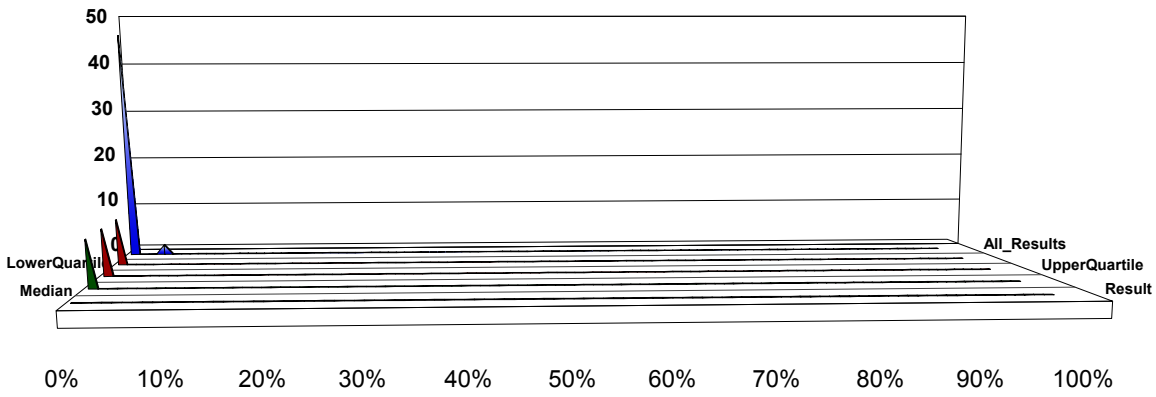
Granulocytes PNH Clone - CD66b



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Method Breakdown

RBC PNH Clone

Flow Cytometer	Median	Lower Quartile	Upper Quartile	Returns
CD55				
All	0.00	0.00	0.00	15
BD	0.00	0.00	0.03	12
CD59				
All	0.00	0.00	0.00	123
BD	0.00	0.00	0.00	84
Coulter	0.00	0.00	0.00	38

Antibody Manufacturer	Median	Lower Quartile	Upper Quartile	Returns
CD55				
All	0.00	0.00	0.00	15
CD59				
All	0.00	0.00	0.00	123
BD Biosciences	0.00	0.00	0.09	16
eBioscience	0.00	0.00	0.00	12
invitrogen	0.00	0.00	0.00	62

Fluorochrome	Median	Lower Quartile	Upper Quartile	Returns
CD55				
All	0.00	0.00	0.00	15
PE	0.00	0.00	0.00	13
CD59				
All	0.00	0.00	0.00	123
PE	0.00	0.00	0.00	96
FITC	0.00	0.00	0.00	26

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Method Breakdown
Granulocytes PNH Clone

Flow Cytometer	Median	Lower Quartile	Upper Quartile	Returns
CD157				
All	0.00	0.00	0.00	13
CD16				
All	0.00	0.00	0.00	33
BD	0.00	0.00	0.00	22
Coulter	0.00	0.00	0.00	10
CD24				
All	0.00	0.00	0.00	94
BD	0.00	0.00	0.00	66
Coulter	0.00	0.00	0.00	27
CD55				
All	0.00	0.00	0.00	19
BD	0.00	0.00	0.05	11
CD59				
All	0.00	0.00	0.00	18
BD	0.00	0.00	0.12	11
CD66b				
All	0.00	0.00	0.00	25
BD	0.00	0.00	0.02	18
FLAER				
All	0.00	0.00	0.00	119
BD	0.00	0.00	0.00	82
Coulter	0.00	0.00	0.00	36

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Antibody Manufacturer	Median	Lower Quartile	Upper Quartile	Returns
CD157				
All	0.00	0.00	0.00	13
CD16				
All	0.00	0.00	0.00	33
BD Biosciences	0.00	0.00	0.00	14
Beckman Coulter	0.00	0.00	0.00	11
CD24				
All	0.00	0.00	0.00	94
BD Biosciences	0.00	0.00	0.00	28
Beckman Coulter	0.00	0.00	0.00	40
Pharmingen	0.00	0.00	0.00	21
CD55				
All	0.00	0.00	0.00	19
BD Biosciences	0.00	0.00	0.00	10
CD59				
All	0.00	0.00	0.00	18
CD66b				
All	0.00	0.00	0.00	25
BD Biosciences	0.00	0.00	0.07	11
FLAER				
All	0.00	0.00	0.00	119
Other	0.00	0.00	0.00	64
Protox	0.00	0.00	0.00	43

Fluorochrome	Median	Lower Quartile	Upper Quartile	Returns
CD157				
All	0.00	0.00	0.00	13
PE	0.00	0.00	0.00	12
CD16				
All	0.00	0.00	0.00	33
CD24				
All	0.00	0.00	0.00	94
PE	0.00	0.00	0.00	69
CD55				
All	0.00	0.00	0.00	19
PE	0.00	0.00	0.00	13
CD59				
All	0.00	0.00	0.00	18
PE	0.00	0.00	0.00	11
CD66b				
All	0.00	0.00	0.00	25
FITC	0.00	0.00	0.00	17
FLAER				
All	0.00	0.00	0.00	119
FITC	0.00	0.00	0.00	32
AlexaFluor 488	0.00	0.00	0.00	87

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Paroxysmal Nocturnal Haemoglobinuria

Participant: 42981 **Trial No: 151604**

Date Issued: 08-February-2016 **Closing Date: 26-February-2016**

Your Results

Sample: 084

Trial Comments

This trial was issued to 155 participants

Sample Comment
This sample was manufactured from stabilised whole blood spiked with stabilised PNH material from a consented patient.

Target Cells	Your Result	Median Result	Lower Quartile	Upper Quartile	Number of Returns
RBC PNH Clone - CD59		1.69	1.40	2.04	121
RBC Type II Cells - CD59		0.64	0.48	0.84	113
RBC Type III Cells - CD59		1.06	0.81	1.30	114
Granulocytes PNH Clone - CD24	1.50	5.20	4.70	5.82	96

Performance Monitoring

Sample 084

	Consensus	Your Result	Classification	Running Classification
RBC	Clone Present	Not Routinely Tested		Red 3
WBC	Clone Present	Clone Present	Within Consensus	Green 1

1 = All Samples Within Consensus across last 3 samples
2 = 1 Sample Outwith Consensus across last 3 samples
3 = 2 or more Samples Outwith Consensus across last 3 samples
= Not enough samples to determine Running Consensus

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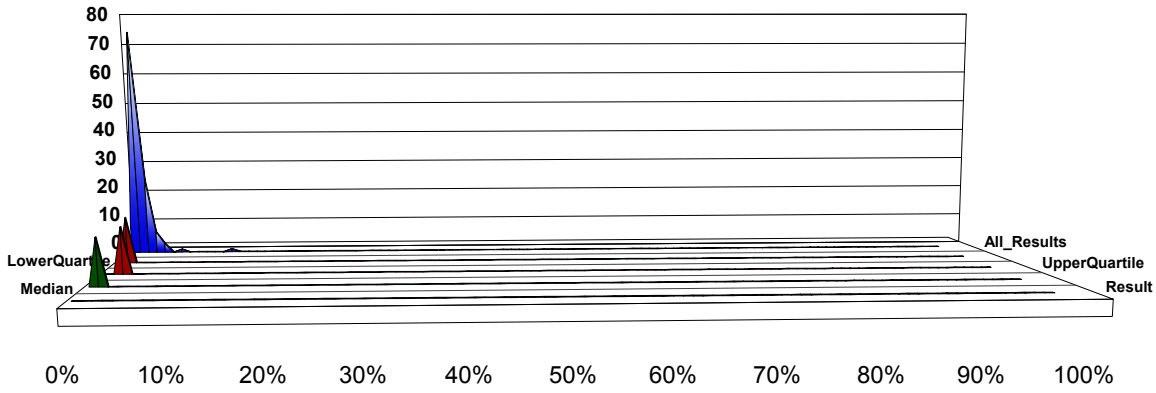
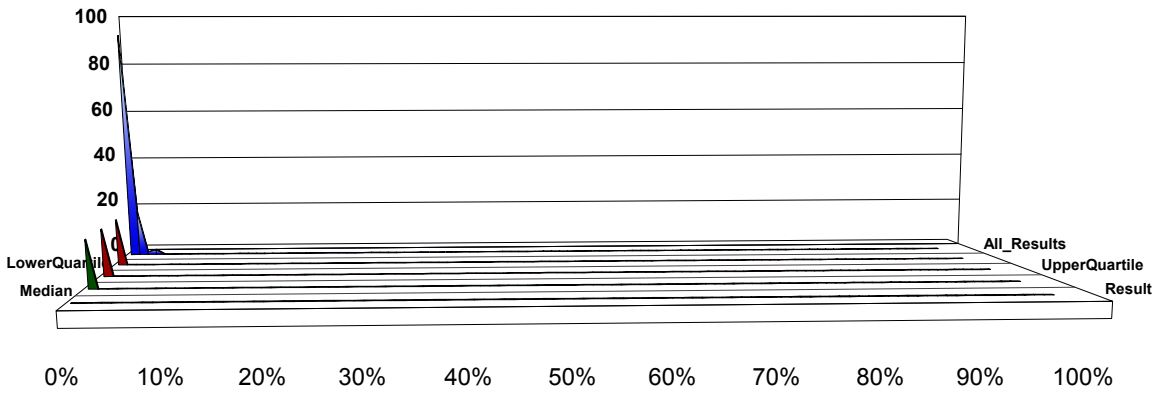
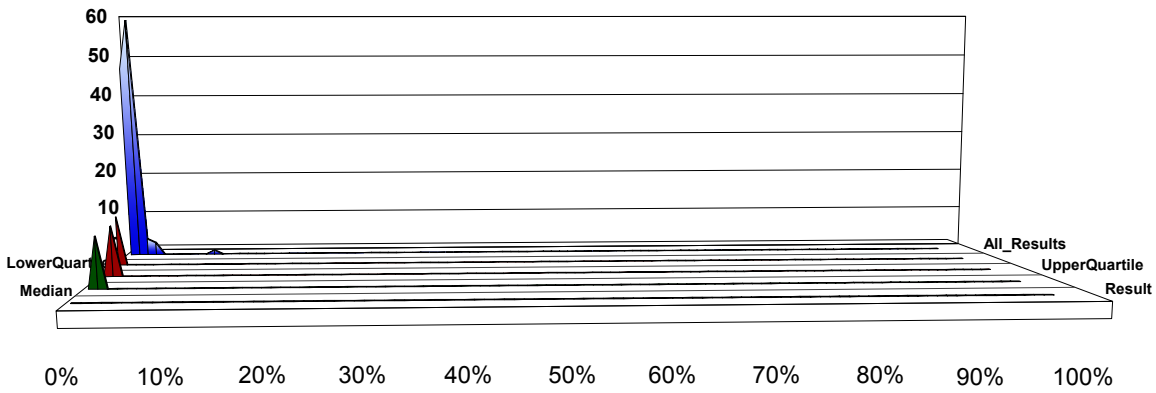
RBC PNH Clone - CD59



RBC Type II Cells - CD59



RBC Type III Cells - CD59



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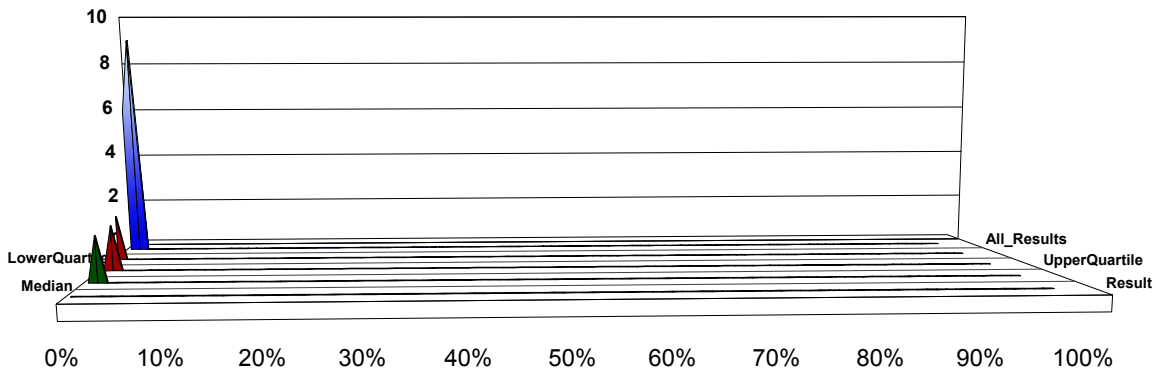
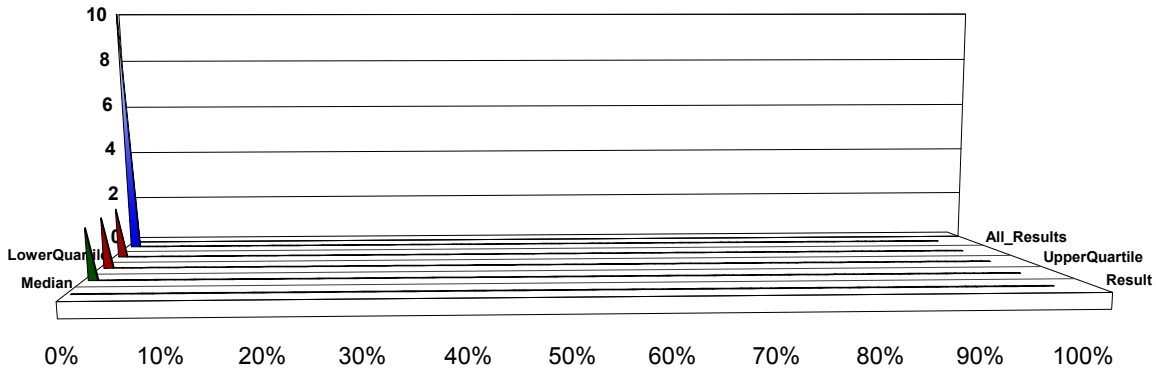
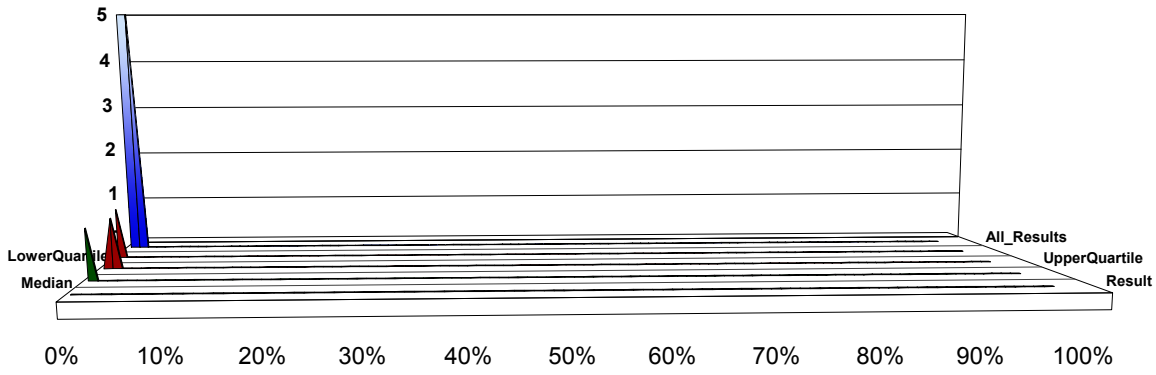
RBC PNH Clone - CD55



RBC Type II cells - CD55



RBC Type III cells - CD55



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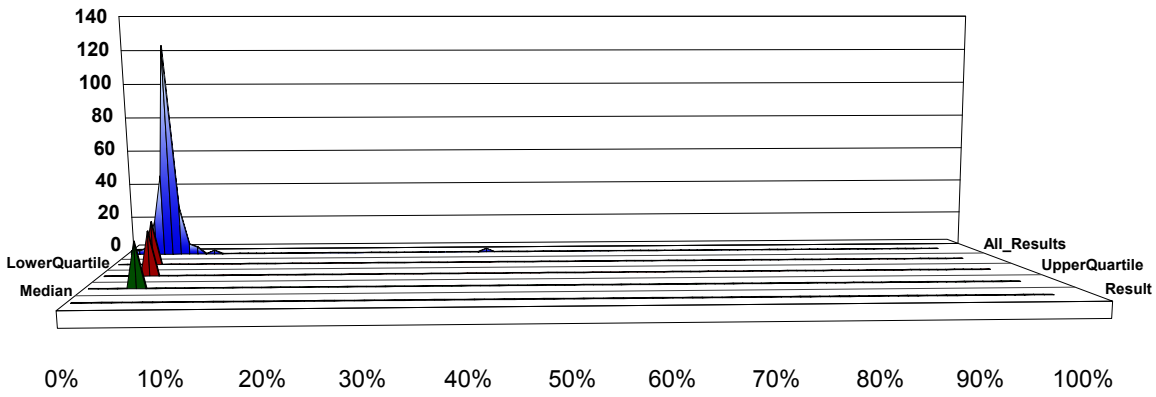
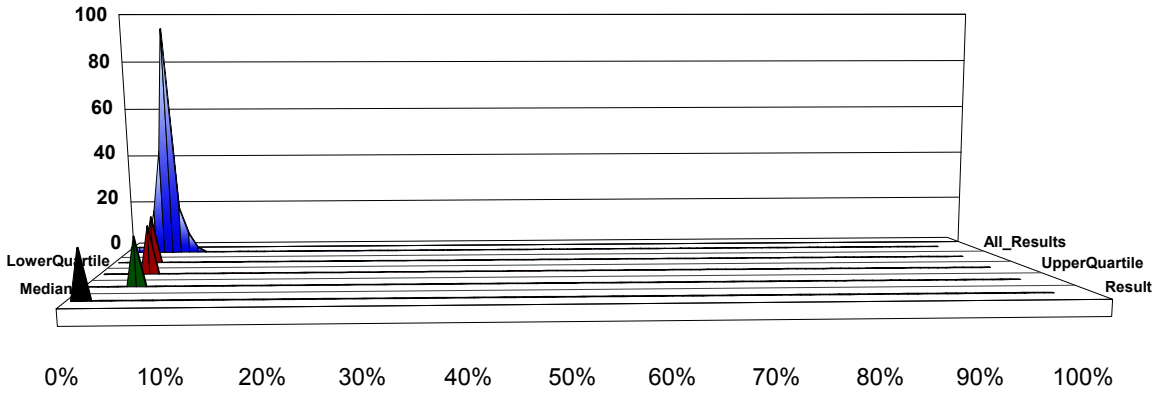
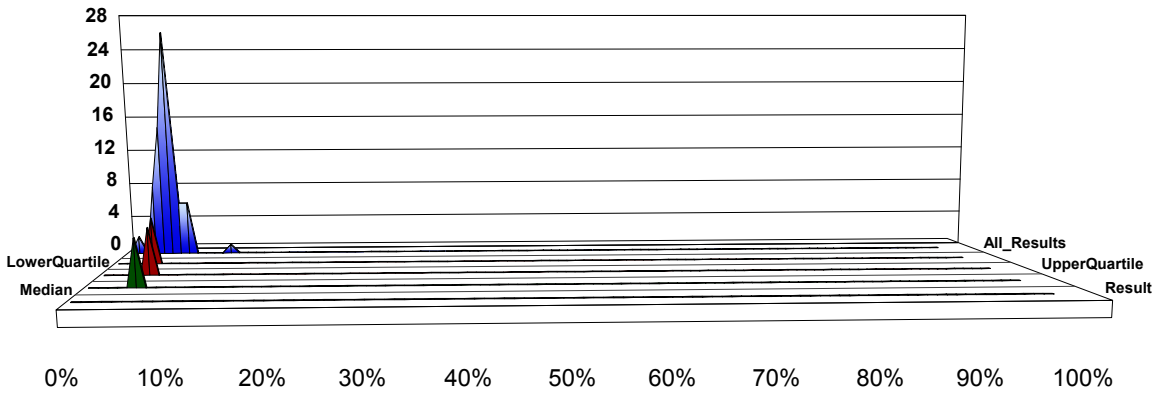
Granulocytes PNH Clone - FLAER



Granulocytes PNH Clone - CD24



Granulocytes PNH Clone - CD16



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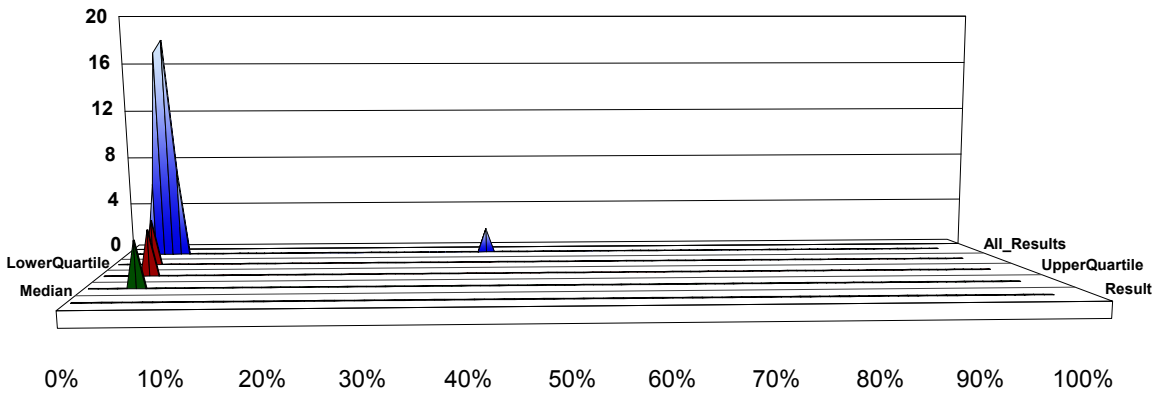
Granulocytes PNH Clone - CD66b



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Method Breakdown

RBC PNH Clone

Flow Cytometer	Median	Lower Quartile	Upper Quartile	Returns
CD55				
All	1.35	0.67	1.60	15
BD	1.23	0.68	1.60	12
CD59				
All	1.69	1.40	2.04	121
BD	1.68	1.40	2.07	83
Coulter	1.80	1.40	2.00	37

Antibody Manufacturer	Median	Lower Quartile	Upper Quartile	Returns
CD55				
All	1.35	0.67	1.60	15
CD59				
All	1.69	1.40	2.04	121
BD Biosciences	1.89	1.27	2.88	16
eBioscience	1.91	1.70	2.85	12
invitrogen	1.69	1.40	2.01	60

Fluorochrome	Median	Lower Quartile	Upper Quartile	Returns
CD55				
All	1.35	0.67	1.60	15
PE	1.35	0.70	1.60	13
CD59				
All	1.69	1.40	2.04	121
PE	1.70	1.40	2.10	94
FITC	1.57	1.15	1.95	26

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Method Breakdown
Granulocytes PNH Clone

Flow Cytometer	Median	Lower Quartile	Upper Quartile	Returns
CD157				
All	5.00	4.67	5.52	13
CD16				
All	5.20	4.00	5.70	33
BD	5.30	4.81	5.65	22
Coulter	4.60	3.95	5.96	10
CD24				
All	5.20	4.70	5.82	96
BD	5.16	4.75	5.69	67
Coulter	5.34	4.32	5.89	28
CD55				
All	5.10	4.63	5.41	18
BD	5.10	4.73	5.86	10
CD59				
All	5.24	4.62	5.87	18
BD	5.20	4.55	6.36	11
CD66b				
All	5.00	4.43	5.83	26
BD	5.00	4.43	5.83	18
FLAER				
All	5.30	4.86	5.82	121
BD	5.20	4.90	5.74	83
Coulter	5.37	4.69	5.88	37

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Antibody Manufacturer	Median	Lower Quartile	Upper Quartile	Returns
CD157				
All	5.00	4.67	5.52	13
CD16				
All	5.20	4.00	5.70	33
BD Biosciences	5.33	5.01	6.01	14
Beckman Coulter	4.70	3.97	5.24	11
CD24				
All	5.20	4.70	5.82	96
BD Biosciences	5.10	4.62	5.50	29
Beckman Coulter	5.37	4.70	5.90	41
Pharmingen	5.16	4.80	5.90	21
CD55				
All	5.10	4.63	5.41	18
BD Biosciences	5.00	4.66	5.36	11
CD59				
All	5.24	4.62	5.87	18
CD66b				
All	5.00	4.43	5.83	26
BD Biosciences	4.70	4.45	5.64	11
FLAER				
All	5.30	4.86	5.82	121
Other	5.20	4.81	5.79	66
Protox	5.40	5.00	5.90	43

Fluorochrome	Median	Lower Quartile	Upper Quartile	Returns
CD157				
All	5.00	4.67	5.52	13
PE	5.00	4.63	5.43	12
CD16				
All	5.20	4.00	5.70	33
CD24				
All	5.20	4.70	5.82	96
PE	5.22	4.86	5.82	69
CD55				
All	5.10	4.63	5.41	18
PE	5.00	4.60	5.45	13
CD59				
All	5.24	4.62	5.87	18
PE	5.29	4.70	5.85	11
CD66b				
All	5.00	4.43	5.83	26
FITC	5.00	4.60	5.30	17
FLAER				
All	5.30	4.86	5.82	121
FITC	5.20	4.82	5.62	32
AlexaFluor 488	5.30	4.90	5.90	89

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Sample 083

This sample was a normal whole blood sample and contained no PNH clone.

The consensus result for this sample was **Clone Absent** for both Red Cell and Granulocyte clones. 16 participants identified a red cell clone with the majority of these were <1% clone size and reported as clone absent and therefore within consensus. However, one centre identified a Type 2 red cell clone of 2.9% recording this as clone absent. Only one centre reported their results as being clone present (clone size 0.4%) and was out of consensus.

13 participants identified a granulocyte clone on at least one of their markers, 10 of these were reported as being clone absent with the majority (9/10) being <1% clone size, however one centre identified granulocyte clones of 5.4% and 9.1% on two of their markers and recorded these clone absent. There were 3 centres that reported their results as clone present (clone size 0.08%, 0.1% and 4%) and these were out of consensus.

Sample 084

This sample was PNH material spiked into a unit of normal whole blood; the median values of the results returned accurately reflected those obtained at pre-issue testing.

The consensus result for this sample was **Clone Present** for both Red Cells and Granulocytes. Only 3 participants failed to identify a red cell PNH clone recording their results as clone absent and were out of consensus. One additional centre was out of consensus having identified a red cell clone of 1.2% and recorded this as clone absent.

Only one centre did not identify a granulocyte PNH clone and recorded their results as clone absent and was therefore out of consensus. Another centre identified clones of 5%, 6.3% and 6.5% on their markers yet recorded these as clone absent and was also out of consensus.

11 centres did not return any results for this send out.

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Information with respect to compliance with standards BS EN ISO/IEC 17043:2010

4.8.2 a) The proficiency testing provider for this programme is:
UK NEQAS for Leucocyte Immunophenotyping
Pegasus House, 4th Floor Suite
463A Glossop Road
Sheffield, S10 2QD
United Kingdom
Tel: +44 (0) 114 267 3600, Fax: +44 (0) 114 267 3601
e-mail: nicola.rose@ukneqasli.co.uk

4.8.2 b) The coordinators of UK NEQAS LI programmes are Prof David Barnett and Mr Liam Whitby.

4.8.2 c) Person(s) authorizing this report:
Prof David Barnett, Director or Mr Liam Whitby, Operations Manager of UK NEQAS LI

4.8.2 d) No activities in relation to this EQA exercise were subcontracted.

4.8.2 g) The UK NEQAS LI Confidentiality Policy can be found in the Quality Manual which is available by contacting the UK NEQAS LI office. Participant details, their results and their performance data remain confidential unless revealed to the relevant NQAAP when a UK participant is identified as having performance issues.

4.8.2 i) All EQA samples are prepared in accordance with strict Standard Operational Procedures by trained personnel proven to ensure homogeneity and stability. Where appropriate/possible EQA samples are tested prior to issue. Where the sample(s) issued is stabilised blood or platelets, pre and post stability testing will have proved sample suitability prior to issue.

4.8.2 l), n), o), r) & s) Please refer to the UK NEQAS LI website at www.ukneqasli.co.uk for detailed information on each programme including the scoring systems applied to assess performance (for BS EN ISO/IEC 17043:2010 accredited programmes only). Where a scoring system refers to the 'consensus result' this means the result reported by the majority of participants for that trial issue. Advice on the interpretation of statistical analyses and the criteria on which performance is measured is also given. Please note that where different methods/procedures are used by different groups of participants these may be displayed within your report, but the same scoring system is applied to all participants irrespective of method/procedure used.

4.8.2 m) We do not assign values against reference materials or calibrants.

4.8.2 q) Details of the programme designs as authorized by The Steering Committee and Specialist Advisory Group can be found on our website at www.ukneqasli.co.uk. The proposed trial issue schedule for each programme is also available.

4.8.2 t) If you would like to discuss the outcomes of this trial issue, please contact UK NEQAS LI using the contact details provided.

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